

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application n° PCT/FR2004/002890	International filing date (day/month/year) 10.11.2004	Priority date (day/month/year) 10.11.2003	
International Patent Classification (IPC) or both national classification and IPC			
A61K9/22			
Applicant: NOUVEAUX PRODUITS PHARMACEUTIQUES et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 11 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			

Date of submission of the demand of international preliminary examination	Date of completion of this report:
05.08.2005	07.03.2006
Name and postal address of authority conducting international preliminary examination European patent office D-80298 Munich Tel : +49 89 2399 - 0 Tx: 523656 epmu d Fax : +49 89 2399 - 4465	Authorized officer Villa Riva, A Telephone n° : +49 89 2399-8404

10/579045

10 MAY 2006

International application n°

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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion is based on a translation from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1 (b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements* of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the description, pages

1-45 as originally filed/furnished

the claims, No.

1-36 as originally filed/furnished

the drawings, sheets

1/5-5/5 as originally filed/furnished

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to the sequence listing (*specify*):
4. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application

claims Nos: 35,36 (ia)

because:

the said international application, or the said claims Nos. 35,36 (ia) relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for said claim Nos.

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form has not been furnished

does not comply with the standard.

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details.

**INTERNATIONAL PRELIMINARY
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Box No. V Reasoned statement under Rule 35.2, with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	1-36
	No:	Claims	
Inventive step	Yes:	Claims	1-36
	No:	Claims	
Industrial applicability:	Yes:	Claims	1-34
	No:	Claims	

2. Citations and explanations (Rule 70.7) :

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY
(SEPARATE SHEET)**

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Concerning point III

No formulation of opinion with respect to novelty, inventive activity and possibility of industrial application.

This Administration considers that the purpose of claims 35 and 36 is defined by the provisions of rule 67.1 (iv) in the PCT. This is why no opinion will be formulated about whether or not the purpose of these claims is suitable for industrial application (article 34(4) a) i) PCT).

Concerning point V

Justified statement with respect to novelty, inventive activity and possibility of industrial application; references and explanations to support this statement

References are made to the following documents:

D1: US-A-5 783 215

D2: EP-A-0 361 874

D3: US-A-6 077 533

If no other information is given, reference is made to the sections referred to in the International Search Report.

The two documents D1 and D2 refer to a process in which neutral nuclei (non-similar) are coated by a layer including a mix of polymers and active constituents applied by spraying. The results are micro pellets that can be used to obtain pharmaceutical forms for oral administration, for example by direct compression. However, they are not provided with two separate layers as in this application.

This is why the purpose of claims 1-36 appears to be novel compared with D1 and D2 according to Art. 33(1) and (2) PCT.

D3 is the closest prior art. It describes pellets, for example of morphine sulfate at a low dose (or a high dose depending on the required rate). The difference from this application is that there is no distinguishable polymer layer.

The problem is to obtain formulations with a good profile of active constituents released at

**WRITTEN OPINION OF THE INTERNATIONAL
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(SEPARATE SHEET)**

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low doses. Considering the good results obtained regarding modulation of the release rate and advantages in terms of production simplicity, the presence of an inventive activity as required by Art. 33(1) and (3) in the PCT can be recognized for claims 1 - 36.

There is no unified criterion in Member States of the PCT for determining if claims 35, 36 are suitable for industrial application. Patentability may also depend on the manner in which the claims were formulated. Thus, the European Patent Office does not consider the purpose of the claims for use of a compound for medical purposes as suitable for industrial application. On the other hand, claims related to a known compound may be accepted for first use for medical purposes and claims related to the use of such a component may be accepted for manufacturing of a drug for a new medical treatment.

Concerning point VIII

Observations relating to international application

The term Carbopol® used in claim 10 is a registered trademark and has no precise meaning because it is not accepted internationally as a standard descriptive term. Therefore, it/they make(s) the definition of the subject of this claim ambiguous (PCT article 6).